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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,229	09/26/2003	Vinod Sharma	P0011083.00	2880

27581 7590 10/04/2007

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3766	
MAIL DATE	**DELIVERY MODE**
10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,229	SHARMA, VINOD	
	Examiner	Art Unit	
	Frances P. Oropeza	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/30/07 (RCE and Amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 25-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/07 has been entered.

Response

2. The Applicant amended at least the independent claims in the response filed 7/30/07, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

3. Claims 1-23 and 25-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,167,308 ("DeGroot") in view of U.S. Patent No. 6,400,986 ("Sun et al.").

DeGroot discloses a method of delivering ATP regimens comprising:

(a) upon detection of a tachycardia episode, delivering an exploratory ATP sequence of pacing pulses to the heart chamber to elicit a paced depolarization of the heart chamber upon delivery of at least the last delivered ATP pulse (see, for example, col. 2, lines 46-61 in which two series of short series of ATP pulses are delivered);

(b) measuring an exploratory return cycle length (RCL) from the last delivered exploratory ATP sequence pacing pulse to the next detected intrinsic depolarization (after delivery of the second series of pulses, the IMD measures the return cycle T4 as described at col. 2, lines 61-63);

(c) formulating an ATP regimen having ATP cycle length parameters, wherein the cycle length is formulated as a function of the measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3, the device either continues delivery of pacing pulses separated by intervals T2 or switches to different therapy as described at col. 2, lines 63-66. Since the applied inter-pulse interval varies depending upon whether the measured return cycle T4 increases or does not increase with respect to T3, the ATP cycle length is considered to be "formulated as a function of the measured exploratory RCL"); and

(d) delivering the ATP regimen to the heart chamber.

With respect to claim 19, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

With respect to claims 1, 2, 13, 19-21, 33 and 35, DeGroot teaches formulating an ATP regimen having ATP parameters defined as a function of a measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3,

the device either continues delivery of pacing pulses separated by intervals T2 or switches to different therapy as described at col. 2, lines 63-66). In the method disclosed in DeGroot, if the return cycle T4 increases in comparison to return cycle T3, the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia. However, if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30). DeGroot fails to teach that the next available therapy may be selected based upon previously successful ATP regimens that successfully terminated a tachycardia when similar return cycles were calculated. Sun et al. teaches an IMD with ATP capability that is programmed to deliver ATP therapy upon detection of a tachycardia by employing a pacing regimen selected from a library, or database, of previously successful or unsuccessful pacing protocols (see col. 2, lines 20-53). The recorded protocols include the exploratory RCL, as the exploratory RCL is a parameter of the pacing protocol (see col. 2, lines 20-26; col. 3, lines 14-36; col. 5 @ 61-67). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select the next available therapy based upon previously successful ATP regimens that successfully terminated a tachycardia as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as possible by selecting a pacing regimen that successfully terminated a tachycardia when similar return cycles were calculated.

With respect to claims 3, 21, 25, and 36, Sun et al. teach the use of success/failure counters associated with each pacing protocol contained in the library. After each attempt of

ATP therapy using a particular protocol, the relevant counter is incremented to indicate the success or failure of the protocol in terminating the arrhythmia (see example, col. 2, lines 54-59).

With respect to claims 4-7, 15-16, 22, 26-29, and 37-38, DeGroot detects whether a tachycardia is occurring (see, for example, step 200 of Fig. 4a) and also detects whether the tachycardia terminates in response to delivered ATP pacing therapy (see col. 5, lines 55-60). Detection of whether the tachycardia has terminated includes determining a post-ATP rate (see col. 5, lines 55-60). Although not explicitly stated, DeGroot utilizes a pre-ATP rate to detect whether a tachycardia episode is occurring (in the alternative, Applicant admits that it is known for a ICD to employ tachycardia classification algorithms that utilize detected heart rates in order to detect a tachycardia; see Applicant's specification at page 2. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the IMD of DeGroot to detect the pre-ATP rate in order to detect a tachycardia as is well known in the art in order to accurately detect a tachycardia condition). If the post-tachycardia rate is still determined to be a tachycardia but is different from the pre-ATP rate (i.e., if the tachycardia rate is decelerating, the same, or accelerating), it would have been obvious to one having ordinary skill at the time of applicant's invention to modify the combined IMD of DeGroot and Sun et al. to record in the result table/database whether the unsuccessful pacing regimen resulted in accelerating or non-accelerating tachycardia rate in order to provide a physician with more information regarding the effect of a particular pacing regimen on the patient's tachycardia condition. Further, if the tachycardia condition is deemed to be accelerating, it is known in the art that a cardioversion or defibrillation may be required (see, for example, U.S. Patent No. 4,998,974 to Aker).

With respect to claims 8-10, 18, and 30-32, DeGroot discloses that if the return cycle T4 increases in comparison to return cycle T3, the IMD increases the number of ATP pulses delivered (the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia). In addition, DeGroot discloses that if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30). The new pacing regimen may include reducing the inter-pulse pacing interval (see col. 6, lines 20-25).

With respect to claims 11-12, 14, 17, 23, and 34, Sun et al. teaches that the information contained in the success/failure counters may be used to calculate a success/failure ratio (see, for example col. 2, lines 59-63 and col. 6, lines 1-37). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select a therapy having the highest stored efficacy as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as possible.

With respect to claims 19-38, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot and or Sun et al. (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

With respect to storing the measured exploratory RCL used in formulating the delivered ATP regimen and storing the delivered ATP regimen, DeGroot teaches storing in random access memory the variable control parameters for the device, and the derived values such as the time intervals separating tachyarrhythmia pulses and the corresponding high rate pacing intervals. (col. 3, lines 48-55). The derived time intervals stored in random access memory are accepted to be T3 and T4 (col. 2, lines 52-63). T4 is the return cycle, the return cycle defined as the time period between a delivered anti-tachycardia pacing pulses and the next subsequent spontaneous depolarization (col. 1, lines 63-66). Sun et al. is included in the rejection of record to teach that the next available therapy may be selected based upon previously successful ATP regimens that successfully terminated a tachycardia when similar return cycles were calculated.

In the arguments filed 7/30/07the Applicant asserts the Examiner has agreed that DeGroot fails to teach or suggest storing a measured exploratory RCL. The Examiner respectfully disagrees. The Examiner has made no such statement. The Examiner's position relative to storing the measured exploratory RCL, as discussed in the previous paragraph, is that DeGroot teaches storing a measured exploratory RCL.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carl H. Layno
CARL LAYNO
PRIMARY EXAMINER

Frances P. Oropeza
Patent Examiner
Art Unit 3766

FPO
9/30/07